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10/533,063	05/12/2006	Robert Short	P-7714	3122

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EXAMINER	
HEYER, DENNIS	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,063	SHORT ET AL.	
	Examiner	Art Unit	
	DENNIS HEYER	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/11/2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-25 and 33-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-25 and 33-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of Applicant's remarks and amendments filed January 11, 2011. Acknowledgement is made of the amendment to independent Claim 1, method step v), which now recites "incubating said non-modified plasma polymer coated surface with said carbohydrate molecule in its native form, whereby, during incubation, the carbohydrate molecule is passively adsorbed to said non-modified plasma polymer coated surface, in the absence of albumin or salts, binds with said ~~on the~~ non-modified plasma polymer coated surface and is thereby immobilized on said non-modified plasma polymer coated surface in the absence of albumin or salts, such that the carbohydrate molecule remains in its native form, is not contaminated and retains its biological activity".

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1, 3 – 25 and 33 – 38 are currently pending

Maintained Rejections

Claim rejections – 35 USC § 112 – 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3 – 25 and 33 – 38 *remain* rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained but is modified slightly as necessitated by Applicant's amendment to Claim 1.

Applicant has amended Claim 1 to recite, in method step v) incubating said non-modified plasma polymer coated surface with said carbohydrate molecule in its native form, whereby, during incubation, the carbohydrate molecule is passively adsorbed to said non-modified plasma polymer coated surface, in the absence of albumin or salts, binds with said ~~on the~~ non-modified plasma polymer coated surface and is thereby immobilized on said non-modified plasma polymer coated surface in the absence of albumin or salts, such that the carbohydrate molecule remains in its native form, is not contaminated and retains its biological activity.

Claim 1 remains indefinite because the claim still requires that the carbohydrate molecule is passively adsorbed in its native form *in the absence of albumin salts* but, as pointed out in the Office Action mailed October 12, 2010, the single working example disclosed in the specification (Adsorption of Heparin, page 16) *contains salts* (PBS, phosphate buffered saline). Further, with regard to the limitation 'is not contaminated',

the specification states "it is preferred that the polysaccharide is not contaminated (e.g. with albumin or salts). Accordingly, as noted in the previous Office Action, when read in light of the specification, there, *still* appears to be a contradiction between amended Claim 1 and the working example regarding the limitation 'in the absence of albumin or salts' and 'is not contaminated'. Thus, the claim is indefinite because it is unclear which salts are excluded and which salts may be included (for example, PBS, in the disclosed working Example) in amended Claim 1, step v.

Claim rejections – 35 USC § 112 – 1st Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3 – 25 and 33 – 38 *remain* rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained but is modified slightly as necessitated by Applicant's amendment to Claim 1.

This maintained enablement rejection is based upon the limitation in method step v) of amended Claim 1 drawn to "incubating said non-modified plasma polymer coated

surface with said carbohydrate molecule in its native form, whereby, during incubation, the carbohydrate molecule is passively adsorbed to said non-modified plasma polymer coated surface, in the absence of albumin or salts, binds with said ~~on the~~ non-modified plasma polymer coated surface and is thereby immobilized on said non-modified plasma polymer coated surface in the absence of albumin or salts, such that the carbohydrate molecule remains in its native form, is not contaminated and retains its biological activity".

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

Amended Claim 1 is drawn to a method to immobilize at least one type of carbohydrate molecule to a plasma polymer coated surface comprising steps i) – v). Claim 1 (step v), as amended, still requires incubating the at least one type of carbohydrate molecule in its native form, *in the absence of albumin or salts*, such that said carbohydrate is passively adsorbed on the surface and thereby immobilized. Claim 1 also requires that the carbohydrate is not contaminated and retains its biological activity. It is noted that page 6, 2nd paragraph of the present specification states "it is preferred that the polysaccharide is not contaminated (e.g. with albumin or salts)". Accordingly the limitation "is not contaminated" will be considered a genus of the contaminant species "albumin or salts".

The claim is broad, encompassing any monomer source from which a plasma polymer coating may be created and any carbohydrate molecule in its native form.

Thus, the claims taken together with the specification imply that the recited method will immobilize a carbohydrate in its native form to a plasma polymer coated surface in the absence of contaminants (e.g. albumin or salts).

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The prior art teaches a method for immobilizing a carbohydrate in its native form (an antibody) to a plasma polymer coated surface (Short *et al.* in WO 01/31339, applied

in the Office Action mailed April 9, 2010). The method of Short teaches the incubation step recited in instant Claim 1 (step v) in the presence of a salt, phosphate buffered saline (PBS) (see page 12. Enzyme Immunoassay, lines 2 – 12). Further, the method of Short is described as an enzyme linked immunosorbent assay, known to those in the art as an ELISA (page 12, line 2). The ELISA method, as noted in "Dako, General ELISA Procedure" (February 2002) requires, in step 1(Coating of Wells with Antibody) the antibody be diluted in buffer 'A' (PBS; See Reagents, A. Coating Buffer).

Finally, the prior art of Yan *et al.* (applied in the Office Action mailed April 9, 2010) teaches immobilization of the carbohydrate heparin to a plasma polymer-coated stent surface by incubating the heparin solution in saline (a salt).

The immobilization methods disclosed by Short (an antibody) and Yan (heparin) are considered to be in their native form and salts are present. Neither Short nor Yan disclose a carbohydrate immobilization method in the absence of salts. Accordingly, in light of the teachings of the references cited above, the state of the art would predict that the method of Claim 1 would require the presence of a salt (such as PBS or saline) to immobilize a carbohydrate in its native form to a plasma-polymer coated surface.

(5) The relative skill of those in the art:

The relative skill of those in the art of methods to bind carbohydrates in their native form to surfaces in the absence of salts can be high, generally that of a Ph.D. scientist. That factor is outweighed, however, by the nature of the art which predicts that methods to immobilize a carbohydrate in its native form to a plasma polymer-coated surface requires a salt.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The present specification discloses "In assays, it is preferred that the polysaccharide is adsorbed pure. Moreover it is preferred that the polysaccharide is not contaminated (e.g. with albumin or salts), or that the immobilisation surface is modified (for example by the binding of a first biomolecule (for example, albumin) that will in turn bind the polysaccharide" (page 12, 2nd paragraph, present specification).

The disclosure of a preference that the polysaccharide is not contaminated by albumin or salts provides guidance in the direction of an assay method in which albumin or salts are not present. However, there are no working examples of an assay method in which salts are not present. The single working example ('Adsorption of Heparin', page 16 of the present specification) reads, in part, as follows:

> **Adsorption of Heparin**
>
> Heparin was adsorbed onto both allylamine coated and uncoated (Manufacturers proprietary treatment) overnight from PBS at room temperature. Following standard ELISA methods, the unbound heparin was washed from the surfaces, and the remaining bound molecules were detected using a biotinylated detector molecule.

The specification has provided guidance for a *preference* for the absence of albumin or salts, however the single working example, which employs 'standard ELISA methods, requires the presence of a salt (PBS). Accordingly, the specification does not

provide guidance, by way of a working example, for a method to immobilize a carbohydrate in its native form to a plasma polymer coated surface in the absence of salts.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the unpredictability of immobilizing a carbohydrate in its native form to a plasma polymer coated surface in the absence of salts, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

Claims 1, 3 – 25 and 33 – 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained but is modified slightly as necessitated by Applicant's amendment to Claim 1.

This written description rejection is based upon the limitation in method step v) of amended Claim 1 drawn to "incubating said non-modified plasma polymer coated surface with said carbohydrate molecule in its native form, whereby, during incubation, the carbohydrate molecule is passively adsorbed to said non-modified plasma polymer coated surface, in the absence of albumin or salts, binds with said ~~on the~~ non-modified

plasma polymer coated surface and is thereby immobilized on said non-modified plasma polymer coated surface in the absence of albumin or salts, such that the carbohydrate molecule remains in its native form, is not contaminated and retains its biological activity".

Applicant has not described the claimed genus of carbohydrate molecules in their native form that are passively absorbed and remain in their native form *in the absence of albumin or salts, or is not contaminated*, in a manner that would indicate they were in possession of the full scope of this genus.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc.,

that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must

describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, Claim 1 is drawn to a method to immobilize at least one type of carbohydrate molecule to a plasma polymer coated surface comprising steps i) – v). Claim 1 (step v), as amended, requires incubating the at least one type of carbohydrate in its native form, *in the absence of albumin or salts*, such that said carbohydrate is passively adsorbed on the surface, remains in its native form, is not contaminated and is thereby immobilized. It is noted that page 6, 2nd paragraph of the present

specification states "it is preferred that the polysaccharide is not contaminated (e.g. with albumin or salts)". Accordingly the limitation "is not contaminated" will be considered a genus of the contaminant species "albumin or salts".

(1) Level of skill and knowledge in the art:

The level of skill in the art of methods to bind carbohydrates in their native form to surfaces can be high, generally that of a Ph.D. scientist. That factor is outweighed, however, by the nature of the art which predicts that methods to immobilize a carbohydrate to a plasma polymer coated surface requires a salt. Further, prior art methods for immobilizing a carbohydrate in its native form (an antibody) to a plasma polymer coated surface (Short *et al.* in WO 01/31339) teaches the presence of a salt, phosphate buffered saline (PBS) (see page 12. Enzyme Immunoassay, lines 2 – 12). Further, the method of Short is described as an enzyme linked immunosorbent assay, known to those in the art as an ELISA (page 12, line 2). The ELISA method, as noted in "Dako, General ELISA Procedure" (February 2002) requires, in step 1(Coating of Wells with Antibody) the antibody be diluted in buffer A (PBS; See Reagents, A. Coating Buffer).

Finally, the prior art of Yan *et al.* (applied in the Office Action mailed April 9, 2010) teaches immobilization of the carbohydrate heparin to a plasma polymer-coated stent surface by incubating the heparin solution in saline (a salt). The immobilization methods disclosed by Short (an antibody) and Yan (heparin) are considered to be in their native form and salts are present. Neither Short nor Yan disclose a carbohydrate immobilization method in the absence of salts

Accordingly, the state of the art would predict that the method of Claim 1 would require the presence of a salt (such as PBS) to immobilize a carbohydrate in its native form to a plasma polymer-coated surface.

(2) Partial structure:

The specification discloses a single working example of a method to immobilize a carbohydrate, heparin, to a plasma polymer coated surface (page 16, Absorption of Heparin). The disclosed working example reads, in part, as follows:

> **Adsorption of Heparin**
>
> Heparin was adsorbed onto both allylamine coated and uncoated (Manufacturers proprietary treatment) overnight from PBS at room temperature. Following standard ELISA methods, the unbound heparin was washed from the surfaces, and the remaining bound molecules were detected using a biotinylated detector molecule.

Accordingly, the specification discloses that the carbohydrate heparin has a structure such that it is immobilized to a plasma polymer coated surface in the presence of a salt, PBS. It is not clear what portion, if any, of a heparin molecule, or any other carbohydrate molecule, in its native form, would be required to be immobilized to said surface in the absence of a salt.

(3) Physical and/or chemical properties and (4) Functional characteristics:

No examples of a method of immobilizing a carbohydrate in its native form to a plasma polymer-coated surface in the absence of salts is disclosed. Carbohydrates, as well as other biomolecules (proteins, nucleic acids) are found within typical bacterium or

mammalian cells (i.e. in their native form) in the presence of a significant amount of salt (Alberts *et al.* in Molecular Biology of the Cell, Garland Publishing, 1983; page 92, see Table 3 – 1, below: inorganic ions).

Table 3–1 Approximate Chemical Compositions of a Typical Bacterium and a Typical Mammalian Cell

	Percent of Total Cell Weight	
Component	*E. Coli* Bacterium	Mammalian Cell
H_2O	70	70
Inorganic ions (Na^+, K^+, Mg^{2+}, Ca^{2+}, Cl^-, etc.)	1	1
Miscellaneous small metabolites	3	3
Proteins	15	18
RNA	6	1.1
DNA	1	0.25
Phospholipids	2	3
Other lipids	—	2
Polysaccharides	2	2
Total cell volume:	2×10^{-12} cm^3	4×10^{-9} cm^3
Relative cell volume:	1	2000

Thus, is not clear what physical or chemical properties of a carbohydrate in its native form are required to practice the claimed method of immobilization in the *absence* of salts. It is also not clear what functional characteristic(s) would be required for a carbohydrate to be immobilized in the absence of salts, to remain in its native state and to retain its biological activity; as required by step v) of Claim 1.

(5) Method of making the claimed invention:

A method of preparing a plasma polymer-coated surface and a method of immobilizing a carbohydrate, heparin, in its native form, in the presence of a salt (PBS) is described. However, the Claim lacks sufficient written description because there is no disclosure of a method of immobilizing any carbohydrate in its native form to a plasma polymer-coated surface in the absence of salts.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that Claim 1 is broad and generic, with respect to all possible carbohydrates, in their native forms encompassed by the claims. The possible structural variations are limitless, encompassing any carbohydrate in its native form that can conceivably be immobilized onto any plasma polymer coated surface. Although the claims may recite some functional characteristics (immobilization), the claims lack written description because there is no disclosure of a correlation between function (immobilization) and carbohydrate structure in its native form, in the absence of salts. Accordingly, the specification lacks sufficient variety of species to reflect this variance in the genus. Merely reciting a preference for immobilization of a carbohydrate in its native form in the absence of a salt does not provide sufficient descriptive support for the myriad of carbohydrate compounds and plasma polymer surfaces embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Response to Arguments

Applicant has amended the method of Claim 1 to require in step (v) incubating said non-modified plasma polymer coated surface with said carbohydrate molecule in its native form, whereby, during incubation, the carbohydrate molecule is passively adsorbed to said non-modified plasma polymer coated surface, in the absence of albumin or salts, binds with said ~~on the~~ non-modified plasma polymer coated surface and is thereby immobilized on said non-modified plasma polymer coated surface in the absence of albumin or salts, such that the carbohydrate molecule remains in its native form, is not contaminated and retains its biological activity.

Applicant argues that "the claims, as amended herein, satisfy the enablement requirement. One of skill in the art, based on reading the claims in light of the specification, would appreciate that the carbohydrate is passively adsorbed directly to the plasma polymerized surface. One of skill in the art would also appreciate that there is no salt/protein interaction between the plasma polymerized surface and the carbohydrate during incubation. Furthermore, one of skill in the art would appreciate that directly binding the carbohydrate to the plasma polymerized surface is patentable over the prior art of record" (Remarks, page 7, 2nd paragraph).

Applicant argues that "the amendments sufficiently clarify tile claims and overcome the Examiner's rejection regarding written description. Applicant concludes

that "One of skill in the art would appreciate that the carbohydrate is directly bound to the non-modified plasma polymerized surface. One of skill in the art would also appreciate that there is no salt/protein interaction between the plasma polymerized surface and the carbohydrate during incubation (Remarks, page 8, 2nd paragraph).

The arguments that the claims, as currently amended, overcome the rejections of Claims 1, 3 – 25 and 33 – 38 112 under 35 U.S.C. 1st paragraph as failing to satisfy the enablement and written description requirements is not found to be persuasive because neither the amendment to claim 1 nor Applicant's arguments address the basis for these rejections. Specifically that the method recited in amended Claim 1 still requires *the absence of albumin and salts*.

Applicant has not addressed why in light of the Wands factor analysis applied in the 35 U.S.C. 1st paragraph enablement rejection (specifically the state of the art that requires the presence of a salt (such as PBS or saline) to immobilize a carbohydrate in its native form to a plasma-polymer coated surface), Claim 1, as amended, enables the claimed method, in *the absence of albumin and salts*.

Applicant has not addressed why in light of the analysis regarding the factors cited in the MPEP, as applied in the 35 U.S.C. 1st paragraph written description rejection, Claim 1, as amended, provides sufficient evidence of possession of a method of the claimed invention, in *the absence of albumin and salts*.

Finally, it is noted that the rejection of Claims 1, 3 – 25 and 33 – 38 under 35 U.S.C. 2nd paragraph for being indefinite is maintained because Applicant has not provided any arguments to overcome this rejection. Applicant should submit an

argument under the heading "Remarks" pointing out disagreements with the examiner's contentions.

Conclusion

Claims 1, 3 – 25 and 33 – 38 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Friday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached at (571)272-2919. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DENNIS HEYER/
Examiner, Art Unit 1628

/Timothy P Thomas/
Primary Examiner, Art Unit 1628